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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,126	12/12/2001	Connie Sanchez	5432/0J951US0	7268

7590 09/29/2005

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,126	SANCHEZ ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5 and 10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~12/12/01~~, ~~2/28/02~~, 11/12/03, 12/22/03, 9/13/04, 2/16/05, 6/22/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2005 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 21, 2003, December 02, 2003, September 13, 2004, February 16, 2005 and June 22, 2005 has been considered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5, 10, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Boegesoe et al., US 4,943,590.

Boegesoe et al., disclose as in current claim 2 wherein the pharmaceutically effective dose is recited as an adequate quantity of escitalopram as in current claims 2, 10 and 15 (disclosed as an enantiomeric formula at column 5 lines 15+) in a unit dose at column 10 line19,

- administering 1-50 mg/day at column 10 line 18, current claims 2, wherein, the pharmaceutical effective dose (column 10 line16),
- wherein the method comprises administering 1.0 to 50 mg/day (current claim 3, 16) at column 8 line 59,

- administering 5-40 mg/day (current claim 4) at column 8 line 60,

- current claims 5 (where if one takes the average weight of a human to be 70 kg and multiply by the least recommended amount given 0.003 would yield 21 mg/day) thereby making claims 5 anticipatory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-5 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boegesoe et al., US 4,943,590 and Bouwer et al., use of the selective serotonin reuptake inhibitor citalopram in the treatment of generalized social phobia, J. affective Disorders 49 (1998) 79-82.

Boegesoe et al., teach as in current claim 2 wherein the pharmaceutically effective dose is recited as an adequate quantity of escitalopram as in current claims 2, 10 and 15 (disclosed as an enantiomeric formula at column 5 lines 15+) in a unit dose at column 10 line19,

- administering 1-50 mg/day at column 10 line 18, current claims 2, wherein, the pharmaceutical effective dose (column 10 line16),
- wherein the method comprises administering 1.0 to 50 mg/day (current claim 3, 16) at column 8 line 59,
- administering 5-40 mg/day (current claim 4) at column 8 line 60,
- current claims 5 (where if one takes the average weight of a human to be 70 kg and multiply by the least recommended amount given 0.003 would yield 21 mg/day) thereby teaching claim 5.

Boegesoe et al., however, did not teach panic attacks as in current claims 11-14. Bouwer teaches administering citalopram, structurally and functionally identical to escitalopram for social phobia a disorder that results in extreme anxiety in social situations. Those who suffer from social phobia experience intense and disabling self-

consciousness in these situations. People with social phobia have an intense and persistent feeling of being watched, judged, and evaluated in a negative manner, and panic attack can be defined as sudden onset of intense apprehension, fearfulness, or terror - is accompanied by physiological changes

. Social phobia is a form of panic attack, for example, talking in public/public speaking, an individual may experience a sudden onset of nervousness when called.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Boegesoe with that of Bouwer to administer the drug to treat panic attacks or disorders such as social phobia, agoraphobia etc.

One of ordinary skill in the art would have known that using the teachings of the above combined prior art to treat panic disorders such as social phobia, agoraphobia etc., would have been successful in doing so, as the combined cited prior art teaches administering citalopram or escitalopram to patient in need thereof for the treatment of panic attacks in its generality or specific panic disorders such as social or agoraphobia.

The cited prior art would have motivated one of skill in the art to select citalopram or escitalopram for the treatment of panic attacks or disorders. They are both structurally and fuctionally similar, used for the treatment of the same type of disorders as shown above, therefore one of ordinary skill in the art would have expected successful results for the treatment of panic attacks or disorders in the selection of either drug.

Thus the claims are deemed prima facia obvious over the cited prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
9/14/05

Christopher S. F. Low

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